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| --- | --- | --- | --- | --- | --- | --- | --- |
| S. No.  | Brief Description of the deviation  | Deviation category \*(choose from list below) | Datedd/mm/yyyy | Corrective action if taken describe briefly  | Date reported to ERB if applicabledd/mm/yyyy | Patient continuation in trial after deviation identified 1 yes2 No | PI initials  |
| deviation occurred  | investigators became aware of deviation |
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**Deviation category**

1. Consent document and process
2. Screening
3. Interventions
4. Randomization
5. Visit schedules /follow up
6. Investigational product IP management
7. Data management and Safety Reporting
8. Others specify \_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Consent**  | **Screening**  | **Interventions**  | **Randomization**  |
| * Most recent ERB-approved consent document not used
* Consent not obtained before initiating study procedures
* consent document not appropriately signed/dates missing
* Wrong version of consent form used
* consent taken by unauthorized person (not on delegation of authority log
* others specify \_\_\_\_\_\_\_\_\_
 | * Inclusion criteria not met but participant was enrolled
* Patient fall in any other exclusion criteria but was enrolled
* Screening Performa incomplete unsigned or unstamped
* Required eligibility labs or assessments were missed before enrollment
* Others specify \_\_\_\_\_\_\_\_\_
 | * Wrong treatment given (not per allocation/randomization)
* Wrong intervention performed
* Missed dose of investigational product
* Study intervention not followed as per protocol schedule
* Required procedures/labs/interventions missed.
* Others specify \_\_\_\_\_\_\_\_\_\_\_
 | * Randomization performed before informed consent
* Participant randomized despite failing eligibility criteria
* Incorrect randomization code used
* Allocation envelope opened out of sequence
* Wrong participant ID entered into randomization system
* Randomization performed outside the permitted time window
* Others specify \_\_\_\_\_\_\_\_\_\_
 |
| **Visit schedules / follow up** | **Investigational product IP management**  | **data management and Safety Reporting**  | **Others**  |
| * Participants missed scheduled visit
* Visit conducted outside protocol-defined time window
* Unscheduled visits not documented in the protocol
* Visits specific tasks / procedures / labs not performed
* Others specify \_\_\_\_\_\_\_\_\_
 | * Incorrect storage temperature or conditions
* IP dispensed without proper documentation
* IP accountability records incomplete or inaccurate
* Others specify \_\_\_\_\_\_\_\_\_
 | * Case Report Form (CRF) incomplete or inconsistent with source documents
* Source documents missing or not updated in real time
* Data entry errors identified after monitoring
* Adverse event not reported within required timeline
* Serious adverse event (SAE) form incomplete or missing
* Missing documentation for safety follow-up assessments
* Others specify \_\_\_\_\_\_\_\_\_\_\_\_
 | Specify \_\_\_\_\_\_\_\_\_\_\_ |